



Department of Health and Human Services

Public Health Service

Food and Drug Administration
Rockville, MD 20857

JUN 2 2009

Re: TYKERB
Docket No. FDA-2007-E-0229
Previously 2007E-0257

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the patent term extension application for U.S. Patent No. 6,713,485 filed by SmithKline Beecham Corporation (DBA GlaxoSmithKline) under 35 U.S.C. § 156. The patent claims TYKERB (lapatinib), new drug application (NDA) 22-059.

In the November 10, 2008, issue of the Federal Register (73 Fed. Reg. 66647), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before May 11, 2009, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: John Lemanowicz
SmithKline Beecham Corp.
Corporate Intellectual Property Department
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Research Triangle Park, NC 27709